



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHP) will hold a meeting that will be open to the public. Information about SACHP and the full meeting agenda will be posted on the SACHP website at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATES: The meeting will be held on Wednesday, May 18, 2016, from 8:30 a.m. until 5:00 p.m. and Thursday, May 19, 2016, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Secretary, SACHP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: SACHP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Wednesday, May 18, followed by opening remarks from Dr. Jerry Menikoff, Director, Office for Human Research Protections (OHRP), and Dr. Jeffrey Botkin, SACHRP Chair. OHRP staff will begin the meeting by presenting a summary of public comment received on the Notice of Proposed Rulemaking on Federal Policy for the Protection of Human Subjects. The Subpart A Subcommittee (SAS) will then present their draft work products, including considerations for single IRB review and minimal risk informed consent models. On Thursday, May 19, the Subcommittee on Harmonization (SOH) will present revisions to their recommendations on clustered randomized trials, the return of individual research results, and benchmarking.

SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research

adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The meeting will adjourn at 4:30 p.m. May 19, 2016. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting.

Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting. Note that public comment should be relevant to agenda topics.

Dated: April 21, 2016.

Julia Gorey, J.D.

Executive Secretary, Secretary's Advisory Committee on
Human Research Protections

Office for Human Research Protections

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